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ISSUANCES

of the

Meat and Poultry Inspection Program

SEPTEMBER 1980



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MPI Bulletin 80-45-A
Checklist of MPI Bulletins

CFR Final Rule
Voluntary Meat and Poultry Plant
Quality Control Systems

UNITED STATES DEPARTMENT OF AGRICULTURE
Food Safety and Quality Service
Meat and Poultry Inspection Program
Washington, D.C. 20250

INFORMATION FOR: MPI Employees and Interested Parties

CHECKLIST OF MPI BULLETINS

This checklist includes active bulletins published on or before August 29, 1980 and obsolete bulletins canceled April 30, 1980, through August 29, 1980. Bulletins not appearing on this list (except those published after August 29, 1980) are obsolete and should be removed from active files.

Number		Orig. Staff	Number		Orig. Staff
Date	Subject	Category Dist. Codes	Date	Subject	Category ^{1/} Dist. Codes
11	Plant Operating Schedules	FO/A	553	Extension of Time for	PLS/F
6/23/72	Working Conditions, Poultry Plants	S-12,S-13 ES-14,S-15 ES-16, ES 16-1, ES 16-2,S-17, S-18 (Poultry Plants)	1/2/74	Cured Meat Product Labeling	Q,P,T,U-U-2
			563	Labeling Frozen Dinners	PLS/F
			1/2/74		Q,P,T,U-U-2
			586	Certified Pork--Trichinae	ISR/G
			1/24/74	Control by Refrigeration	Q,P,T,U-U-2
211	Net Weight Compliance	PLS/G	611	Exports of Horsemeat to the	FPS/J
2/20/73		Q	2/14/74	United Kingdom	P,Q,T,U-U-1
235	Nutritional Labeling	PLS/F	616	MPI Bulletin 367	IC/H
3/15/73		EA-ET, U-U-2	2/22/74		Q,P,T,U-U-2
263	Waste Disposal Permit	FO/B	619	MPI Directive 918.1, Poultry	ISR/C
4/6/73		P,Q,U-2	2/25/74	Carcass Inspection Program	Q
367	Meat Trimmings	PLS/H	629	Sorbitol in Cooked Sausages	PLS/G
8/1/73		Q,P,T,U, U-2	3/5/74		Q,P,T,U-U-2
388	Meat Trimmings	PLS/H	648	Sampling Method for Estab- lishment Not Using the Online	ISR/C
8/10/73		Q,P,T,U	3/20/74	Plan for Ready-to-Cook Young Chickens	Q,P,T,U-U-2
392	Cured Meat Product Labeling	PLS/F	650	Labeling Meat and Poultry	PLS/F
8/10/73		Q,P,T, U-U-2	3/19/74	Products with Nonmandatory Features at Locations Other than Official Establishments	Q,P,T,U-U-2
418	Labeling Standards for Certain Cooked Sausages	PLS/F	670	Operations, Procedures and Equipment	PFE/B
8/31/73		Q,P,T,U-U-2	4/12/74		Q,P,T,A,I,J, K,L,M,N,O
456	Warm Cut-Up and Deboning of Poultry	ISR/D	724	Training in Field Operations	FO/A
10/19/73		Q	6/6/74		EA,EK,EL,EN, EO,P,Q,T
506	Labeling Spices, Flavorings, and Colorings	PLS/F	742	Procedure for Controlling Temperatures of Smoking and/or Drying Rooms in Plants Processing Country Cured Pork Products	ISR/G
12/6/73		Q,P,S,U-U-2	6/21/74		Q,T,U-U-2
542	Labeling USDA Specification Product	PLS/F			
12/26/73		Q,P,T,U-U-2			

Number		Orig. Staff Category	Number		Orig. Staff Category
Date	Subject	Dist. Codes	Date	Subject	Dist. Codes
784 8/5/74	Poultry Carcass Inspection Program--Mature Chickens	ISR/C All MPI Codes	76-41 3/9/76	Amendment to MPI Directive 462.1, Standards of Performance	MFS/A EA,EI,EJ,EM
800 9/4/74	Procedures for Controlling Temperatures of Smoking and/ or Drying Rooms in Plants Proc- essing Dry-Cured Pork Products	ISR/G Q,P,T,U,U-2	76-58 4/15/76	Meat Branding Inks	SS/F A-O,P,Q,S, U,U-2 (Issuances)
809 9/10/74	Perishable, Heat Processed Canned Meat Products	PLS/G Q,P,S,U-U-2	76-60 4/16/76	Labeling Meat Quality & Yield Grades	PLS/F A-O,P,Q,S, U,U-2
816 9/16/74	Nutrition Labeling	PLS/F All MPI Codes	76-65 4/27/76	Protein Multiplier Table Change in the Chemistry Laboratory Guidebook	SS/K A-O,P,Q
911 12/24/74	Labeling Spices, Flavorings, and Colorings	PLS/F Q,P,T,U-U-2	76-79 5/17/76	Label Declarations of Salt or Sodium Content	PLS/F (Issuances)
75-3 1/2/75	Control of Canning Opera- tions Conducted at Official Establishments	ISR/G Q,P,S,T, U-U-2	76-123 8/3/76	MPI-APHIS Management and Communication System Coordination	WSDS/A A-O,Q
75-4 1/2/75	Flexible or Semirigid Retortable Packages	ISR/PLS/F P,Q,S,T, U-U-2	76-136 8/25/76	Import Certification	FPS/J A-O,P,Q,S
75-29 2/11/75	Labeling Required Features	PLS/F P,Q,S,U-U-2	76-145 9/8/76	Clarification of Religious (Buddhist) Requirement	ISR/A A-O,P,Q,S, U,U-2
75-56 3/21/75	Poultry Carcass Inspection Program--Turkeys	ISR/C A-O P,Q,S,T,U, U-2	76-146 9/14/76	Mechanically Deboned Meat	IC/A A-O,P,Q,S,T, U,U-2
75-99 6/26/75	Universal Product Code and Postal Zip Code Added to Labeling	PLS/F A-O,P, Q,S,U	76-170 11/4/76	Application Form for Label Approval	PLS/F A-O,P,Q,S,U
75-105 7/15/75	Asbestos Filters	PFE/B A-O,P, Q,S,U,U-2	76-172 11/11/76	Staff Functions-Technical Services	STS/A A-O,P,Q
75-129 9/2/75	Jar Closure - Vacuum-Packed Containers	PLS/F A-O,P, Q,S,T,U-U-2	76-175 11/12/76	Livestock Slaughter Data	WSDS/I A-O,P,Q,S,U
75-158 10/29/75	Bratwurst	PLS/H A-O,P, Q,S,U,U-2	76-179 11/17/76	Inspection Requirements for Certain Uncured Beef Products	ISR/G A-O,P,Q,S, T,U,U-2
76-6 1/7/76	Items Used with Meat or Poultry Products that are Unapproved or Approved but Unacceptable	ISR/A A-O,P,Q, S,U	76-198 12/13/76	Utilization of Employees on Short Days	MFS/A A-O,P,Q,S
76-29 2/20/76	Canning Operations and Critical Control Factors	ISR/G A-O,P,Q,S,T, U,U-2	77-13 2/1/77	Guidelines for Semi-Dry Poultry Offal Systems	PFE/B A-O P,Q,S,U,U-2
			77-18 2/9/77	Labeling Meat Quality and Yield Grades	STS/F A-O P,Q,S,U,U-2

Number		Orig. Staff Category	Number		Orig. Staff Category
Date	Subject	Dist. Codes	Date	Subject	Dist. Codes
77-19 2/9/77	Water Reuse	SDS/B A-O P,Q,S,U	78-32 3/14/78	Grade Specifications for Product Purchased Under Government Contract	FSR/F M90,M09-M12, M93-M95,M50
77-20 2/10/77	Labeling Declaration for Proprietary Mixtures	PLS/F A-O,P,Q,S,T, U,U-2	78-35 3/16/78	Establishment Numbers	WSDS/A M90,M09,M10
77-34 3/16/77	Chemical Disinfection in Lieu of 180° F. Water	SDS/B (Issuances)	78-40 3/28/78	Disposition of Contaminated Poultry Carcasses	ISR/C M90,M09-M12, M25,M29,M93
77-65 5/13/77	Thirty-Thirty Test for Percent Pump	SDS/G A-O P,Q,S,U, U-2	78-48 4/19/78	Sequenced Inspection	ISR/C M90,M09-M12, M25,M29
77-66 5/17/77	Energy	PFE/A (Issuances)	78-55 5/12/78	Imprest Fund Payments	MPI/DA/A M90
77-71 5/24/77	Random Sampling Requirements for Residue Monitoring	SS/K A-O,P,Q,S	78-62 6/6/78	Bacon Sampling Program	MPI/DA/G M90,M09-M12, M22,M28,M32, M50
77-76 6/8/77	Cheesefurter Samples for Added Water Compliance	SS/K A-O,P,Q,S	78-63 6/6/78	Implementing Bacon Regulations	PLS/G M90,M09-M12, M22,M28,M32, M50
77-91 6/29/77	Minimum Count	TS/G A-O,P,Q,S,U	78-72 7/14/78	Label Approval for Product Intended for Export	PLS/F M90,M09-M12, M94
77-92 7/6/77	The Implementation of the National Interim Primary Drinking Water Regulations and Their Effect on the Meat and Poultry Inspection Program	PFE/B A-O,P,Q,S,U, U-2	78-74 7/14/78	Implementation of the Bacon Regulations and Sampling Programs	TS/D/G M90,M09-M12, M22,M28,M32, M50
77-94 7/6/77	Representations and War- ranties in Connection with USDA Purchase Programs	TS/A A-O,P,Q,S,U	78-84 8/8/78	Alerting Food and Drug Administration of Repeat Violators	SS/K M90,M09-M12, M50
77-114 8/26/77	Residue Sampling Requirements	SS/K A-O,P,Q,S, U-2	78-85 8/8/78	Bacon Sampling Requirements-- Monitoring and Confirmation	MPI/DA/G M90,M09-M12, M22,M28,M32, M50,M04
77-129 11/11/77	Water Conservation and Sanitation	SDS/B (Issuances)	78-86 8/8/78	Bacon Sampling Requirements-- Retention Phase	MPI/DA/G M90,M09-M12, M22,M28,M32, M50,M04
77-138 12/12/77	Policy Statement on Equal Employment Opportunity	MFS/A M90,M92	78-87 8/10/78	Inspection of Contract Specification Product	FO/G M90,M09-M12, M94,M95,M50
78-16 2/7/78	MPI Directives Checklist	IC/A M90,M07-M12, M50	78-89 8/18/78	Diagnostic Pathology Laboratories	SS/FO/K M90,M09-M12, M04
78-25 2/21/78	Export of Ducks to Singapore	FPS/J M90,M09-M12, M27			

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Date	Subject	Dist. Codes	Date	Subject	Dist. Codes
78-90 8/22/78	Cooked and Roast Beef	ISR/FO/G M90,M09-M12, M18,M28	78-130 12/1/78	Microbiology Laboratories	SS/FO/K M90,M09-M12, M04
78-94 8/23/78	Promotions of Employees Occupying GS-5 Food Inspec- tor Trainee Positions	MFS/A M90,M09-M12	78-131 12/1/78	Threats and Assaults	CS/A M90,M09-M12, M94,M50
78-95 9/7/78	Reporting Swine Sulfonamide Violations	FO/K M90,M09-M10	78-133 12/5/78	Conditions of Use of Accepted Equipment	PFE/B M90,M09-M12, M94,M95,M50
78-96 9/11/78	MPI Headquarters Reorganization	MFS/A M90,M92,M94, M50	79-2 1/8/79	Silicone Sealants and Adhesives	SCIENCE/B M90,M09-M12, M94,M50
78-101 10/5/78	Bacon Sampling Requirements	FO/G M90,M09-M12, M22,M28,M32, M50,M04	79-5 1/24/79	Mechanically Processed (Species) Product	MPSLD/F M90,M09-M12, M28
78-105 10/16/78	Stork Continuous Type Retorts	PFE/B M90,M09-M12, M94,M50	79-12 2/1/79	EEC Requirements for Continuous Chillers	AMPMI/D M90,M09-M13, M25,M27
78-107 10/19/78	Labeling Poultry Breasts	FO/F M90,M09-M12, M15,M17	79-14 2/12/79	Standards of Performance	MFS/A M90,M04
78-108 10/20/78	Veterans' Day 1978	MFS/A M90,M09-M12, M94,M50	79-17 2/28/79	Questionnaire on Government Regulations of Ground Beef	FO/A M90,M92
78-110 10/26/78	Labeling of Proprietary Mixtures	PLS/F M90,M09-M12, M27,M28,M50	79-24 4/6/79	November, 1977 MP Form 23	SCIENCE/I M90,M09-M12, M04
78-111 10/26/78	Reinspection of Poultry Necks and Giblets	AM&PMI/C M90,M09-M12, M25	79-30 4/11/79	Term "ALL" on Labeling	MPSLD/F M90,M09-M12, M25,M27
78-122 11/22/78	Performance Awards Program for Veterinary Medical Officers and Food Inspectors	MFS/A M90,M09-M12	79-31 4/12/79	Post-Mortem Inspection, Young Chickens	TS/C M90,M09-M12
78-126 11/27/78	Export of Poultry to West Germany	FPS/J M90,M09-M12, M25,M27	79-33 4/30/79	Boneless Meat Reinspection of Reconditioned Lots	PPIS/G M90,M09-M12, M18,M28,M50
78-128 11/27/78	Export of Equine Meat	FPS/J M90,M09-M12, M25,M27	79-40 5/4/79	Modified Traditional Inspec- tion	TS-API/C M90,M92,M94, M09-M12
78-129 12/1/78	Cooked Beef from Argentina	FPS/J M90,M09-M11, M14,M04	79-42 5/7/79	Poultry Carcass Inspection Program-Ducks	TS-API/C M90,M09-M12, M50,M94
			79-45 5/10/79	Abnormal Cans and Process Deviations	PPIS/K M90,M09-M12, M15,M18,M94
			79-46 5/10/79	Handling of Meat and Poultry Production Reports	WSDS/I M90,M09-M12


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79-51 5/10/79	Dissemination of Laboratory Results	FO/A M90,M92	79-91 8/23/79	Utilization of Energy	FESS/B M90,M09-M12, M94
79-53 5/11/79	Labeling Information	MPSLD/F M90,M09-M12, M94	79-97 9/18/79	Imported Product from Est. 3, Guatemala	FPS/J M90, M09-M11, M14, M04
79-54 5/14/79	Extension of Time to Implement New Uniform Line Speed Regulation	FO/C M90,M09-M12	79-99 9/26/79	Mailing to Residue Samples	DA-MPI/K M90, M09-M12, M25, M26, M04
79-63 6/13/79	FSQS Form 6200-1	Science/I M90,M09-M12, M04	79-101 9/27/79	New Address for the Special Projects Unit (Formerly Special Projects Laboratory)	Science/K M90, M09-M12, M94
79-65 6/19/79	Spray-on Polyurethane	PFE/B M90,M09-M12, M94,M95,M50	79-104 9/27/79	Export of Poultry to Argentina	FPS/J M90, M09-M12, M25, M27
79-68 6/21/79	Use of Iodine in Processing Water	FESS/B M90,M09-M12, M94,M50	79-105 10-2-79	Use of Plastic Strip Doors	FESS/B M90, M09-M12, M93-M95, M50
79-69 6/29/79	Approval of Partial Quality Control Programs	PPIS/G M90,M09-M12, M94	79-106 10/5/79	Reimbursable Rates	MPI-MFS/A M90, M09-M12, M94
79-72 7/11/79	Carcass Reinspection--Turkey	SISP-TS/C M90,M09-M12, M25	79-107 10/25/79	DES Certification Require- ments for Canada	FPS/J M90, M09-M12, M26, M28
79-73 7/18/79	Mandatory Humane Slaughter	SISP-TS/D M90,M09-M12, M26,M30	79-109 10/30/79	Sources of PCB Contamination	DA/TS/B M90, M09-M12, M94, M50
79-75 7/23/79	Protection of Potable Water Supply on Official Premises	FESS/B M90,M09-M12, M94	79-111 11/8/79	The Reuse of Brine on Product in Impervious Casings	FESD/G M90, M09-M12, M28
79-83 8/3/79	Swab Test on Premises	Science/K M90,M09-M12, M94,M04	79-112 11/14/79	Revocation of DES Certifi- cation Requirements	Science/J M90, M09-M12, M94, M50
79-85 8/8/79	Inspection of Imported Lamb and Mutton Carcasses	PPIS/J M90,M09-M11, M14,M04	79-113 11/19/79	Export Shipments to Singapore Transiting Hong Kong	FPS/J M90, M09-M12, M94
79-87 8/14/79	Poultry Parts with Abdominal Muscle	FPS/J M90,M10,M11, M14,M04	79-115 11/28/79	Testing of Canadian Pork for Sulfonamide Residues	FPS/J M90, M09-M11, M14, M04
79-89 8/23/79	Export to Taiwan	FO-FPS/J M90,M09-M12, M94	79-117 12/4/79	Reduction in Quantity of Contents	MPSLD/F M90, M09-M12, M94

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80-1 1-22-80	Correction to MPI Bulletin 77-114	RES/K M90, M09-M12, M50	80-18 3-18-80	Treatment of Meat with Chlorinated Water	FESD/B M90, M09-M12, M94, M50
80-2 1-29-80	Humane Handling and Slaughtering	SISP/D M90, M09-M12, M16, M26, M50	80-20 3-21-80	Export of High-Quality Beef to the European Economic Community (EEC)	FPS/FO/J M90, M09-M12, M26, M28
80-3 1-29-80	Import of Meat from New Zealand	FPS/FO/J M90, M09-M11, M14	80-22 3-28-80	Deceptive Labeling Practices	MPI/DA/F M90, M09-M12, M94, M50
80-4 1-29-80	Sampling Plan for Turkey Carcasses with Necks	TS/SISP/C M90, M09-M12, M25	80-24 4-17-80	Export to Meat to Austria	FO/FPS/J M90, M09-M12, M26, M28
80-5 1-29-80	Export of Poultry to U.S. Forces in West Germany	FPS/J M90, M09-M12, M25, M27	80-25 4-29-80	Export of Poultry to U.S. Military Japan	FO/FPS/J M90, M09-M12, M25, M27
80-6 2-7-80	Processed Meat and Poultry Products for Export to Saudi Arabia	FPS/FO/J M90, M09-M12, M94	80-26 4-29-80	Export of High-Quality Beef to the European Economic Community (EEC)	FO/FPS/J M90, M09-M12, M26, M28
80-7 2-7-80	Submission of Samples for Biological Residue Analyses	Science/K M90, M09-M12, M50, M04	80-27 5-5-80	Diagnostic Pathology Laboratories	Science/K M90, M09-M12, M04
80-9 2-12-80	Export of Edible Meat/ Byproducts for Animal Food to France	F/PS/J M90, M09-M12, M26, M28	80-29 5-15-80	Labeling of Hams Containing Ground Ham Portions	MPSLD/F M90, M09-M12, M94
80-10 2-25-80	Use of Additional Unidentified Microbial Inhibitors Info. from Laboratories	FO/K M90, M09-M12, M04	80-30 6-18-80	Labeling of Hams Containing Ground Ham Portions	MPSLD/F M90, M09-M12, M94
80-11 2-25-80	Export for Casings to Italy	FPS/FO/J M90, M09-M12, M94	80-31 6-18-80	Guidelines for the Dis- position of Gall-Contamin- ated Giblets	TS/C M90, M09-M12, M15, M94
80-12 2-26-80	Export of Meat to the United Kingdom	FPS/FO/J M90, M09-M12, M26	80-32 6-18-80	Use of Bovine Tongues to Remove Loose Hair from Carcasses	D M90, M09-M12, M16, M26
80-14 3-21-80	Submission of Weekly MP Form 404	IEDM/I M90, M10, M11, M12, M18, M22, M28, M32	80-33 6-30-80	Change of Address and Telephone Numbers for the Midwestern Multidiscip- linary Laboratory	Science/K M90, M09-M12, M04
80-15 3-13-80	Change in Residue Records Sent to Residue Evaluation and Surveillance Division, Science	FO/K M90, M09-M12, M04	80-34 7-1-80	Inspection of Tuberculin Reactors	FO M09-M12, M90
80-16 3-14-80	Recognized Labs for the TEA Nitrosamine Analysis	Science/K M90, M09-M12, M22, M28, M32, M50, M04			

Number		Orig. Staff Category	Number		Orig. Staff Category
Date	Subject	Dist. Codes	Date	Subject	Dist. Codes
80-35 7-1-80	Recognized Labs for PCB Analysis	Science/K M90, M09-M12, M22, M32, M50, M04	80-41 8-5-80	Recognized Laboratories for PCB Analysis	Science/K M90, M09-M12, M22, M28, M32, M50, M04
80-36 7-2-80	Eligibility of U.S. Establishments to Export to Canada	FP/J M90, M09-M12, M94	80-42 8-15-80	Export of Canned and Other Meat or Poultry Products to Greece	FPS/J M90, M09-M12, M94
80-37 7-10-80	Requirements for Certifying Poultry Plants for Export to the United Kingdom (UK)	FPD/J M90, M09-M12, M25, M27	80-43 8-19-80	Export to Canada	FPD/J M90, M09-M12, M94
80-38 7-15-80	Reduction of Injuries	Science/K M90, M09-M12, M50	80-44 8-26-80	Export of Beef Uteri to Japan	FPD/J M90, M09-M12, M26, M28
80-39 7-15-80	Export of Poultry to French Polynesia	FPD/J M90, M09-M12, M25, M27	80-45 8-28-80	Meat Plants Eligible to Export to the United Kingdom	FPD/J M90, M09-M12, M26, M28
80-40 8-5-80	Clarification of MPI Bulletin 80-1	Science/K M90, M09-M12, M50			

BULLETINS DELETED^{1/}

77-78/B
79-116/J
80-8/F
80-13/J
80-17/K
80-19/J
80-21/B
80-23/J
80-28/K
80-26-A/A


Paul Ragan
Director
Regulations Coordination Division

1/ The letter next to the originating staff abbreviations or to the number of the bulletins deleted is the bulletin category.

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

9 CFR Parts 318 and 381

**Voluntary Meat and Poultry Plant
Quality Control Systems**

AGENCY: Food Safety and Quality
Service, USDA.

ACTION: Final rule.

SUMMARY: The Department is amending
the Federal meat inspection regulations

and the poultry products inspection regulations to permit an official meat or poultry establishment to submit its plans for a total plant quality control system (QC) for evaluation by the Food Safety and Quality Service (FSQS). If the Administrator of FSQS deems the system to be adequate and to result in the preparation of meat and poultry products in conformity with requirements of the Federal Meat Inspection Act or the Poultry Products Inspection Act, he will approve the system. The rule also provides for the approval of a partial quality control program in connection with the preparation of individual products or processes, or in connection with part of an operation designed to meet a particular requirement, such as determination of net weight. Provisions are also included for the manufacturing and the test marketing of experimental products.

EFFECTIVE DATE: September 15, 1980.

FOR FURTHER INFORMATION CONTACT:

Mr. Bill F. Dennis, Director, Processed Products Inspection Division, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-3840. The Final Impact Analysis describing the options considered in developing this final rule and the impact of implementing each option is available on request from the above-mentioned individual.

SUPPLEMENTARY INFORMATION:

Significance

This action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been classified "significant."

Background

The Proposal

On September 14, 1979, the Department published in the *Federal Register* (44 FR 53526-53534) a document proposing to permit an official meat or poultry establishment, which has voluntarily developed a total plant quality control system or partial quality control program, to submit its plans and information on such system or program to the Administrator of FSQS for approval. The closing date for receipt of comments was November 13, 1979. However, a notice was published in the *Federal Register* (44 FR 65403) on November 13, 1979, extending the closing date to December 13, 1979.

The proposal contained provisions for the (1) application for total plant quality control or partial plant quality control, (2) evaluation and approval of total

plant quality control or partial plant quality control, (3) termination of approval of total plant quality control or partial plant quality control, and (4) use of a uniform QC logo or symbol on products produced in a plant with an approved QC system. Each of these parts of the proposal is discussed below:

(1) Application for total plant and partial plant quality control.

In order to inform the Department adequately of the establishment's proposed QC system and provide adequate assurances so that the system would function in accordance with the applicable statute and regulations, the proposed general requirements for making application for the Department's approval of a total plant QC system would include:

a. Submission of a letter from the owner or operator of the official establishment to the Administrator of FSQS for the public record stating:

(i) The company's basis and purpose for seeking approval of its QC system and willingness to adhere to the requirements of the system as approved by the Department.

(ii) That all the establishment's data, analyses, and other information generated by its QC system will be available to Department personnel at all times.

(iii) That plant QC personnel will have authority to halt production or shipment of product in cases where other corrective measures have been ineffective.

(iv) That the establishment owner, operator, or appropriate designee will be available for consultation regarding the plant's QC system any time Department personnel find it necessary.

b. If an establishment has one or more full-time persons with primary duties relating to the quality control system, the submission of an organizational chart indicating that such personnel ultimately report to an establishment official whose responsibilities are independent of and not predominantly production.

c. A list identifying those Parts and sections of the Federal meat inspection regulations and those Subparts and sections of the poultry products inspection regulations which are applicable to the operations of the establishment applying for approval of a QC system. This list shall also identify which QC system or part thereof will serve to maintain compliance with the applicable regulations.

d. Detailed information concerning the manner in which the QC system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the

critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the nature of deficiencies the system is designed to identify and control, the process limits at which corrective action will be taken, and the nature of such corrective action.

The general requirements for making application for approval of a partial QC program would include the information specified in item (1)(d) immediately above.

(2) Evaluation and approval of total plant and partial plant quality control.

As proposed, the plant's application for approval of a total plant QC system or a partial QC program would be evaluated by the Administrator of FSQS. If it were to be determined by the Administrator that the total plant QC system or partial QC program would—if carried out as presented—result in finished products being in full compliance with all applicable rules and regulations, the Administrator would approve it and plans would be made for implementation. If the application were denied, the applicant would be informed of the basis for the denial and would be given an opportunity to reapply.

(3) Termination of approval of a total plant QC system or partial plant QC program.

The Administrator would terminate approval of a plant's QC system or program if the establishment is found to have distributed adulterated or misbranded product in commerce. In such cases, opportunity would be provided the plant owner or operator to present views to the Administrator within 30 days of the date of termination and a hearing would be afforded, upon request, in those instances where there is a conflict as to the facts. Termination would also occur if the establishment fails to correct problems in the QC system or program after notice has been given by the Administrator. Prior to such termination, opportunity would be provided the plant owner or operator to present views within 30 days of the date of notice, and a hearing would be afforded, upon request, in those instances where there is a conflict as to the facts.

After termination, an application and request for approval of the same or a modified total QC system would not be evaluated by the Department for at least 6 months from the termination date or for at least 2 months from the termination date in the case of a partial QC program. All facts, data, and information generated during the 6-month period, or 2-month period in the case of a partial QC program, must be included in the new application,

especially such facts, data, and information showing that the problem causing the earlier termination has been rectified.

(4) Use of a uniform QC logo or symbol.

The proposal made a provision for use of a uniform QC logo or symbol as part of the product labeling. Companies utilizing an approved total plant QC system would be permitted to use this logo on the labeling of their product. Consumers would thereby be provided with a means of identifying products produced under an approved QC system.

The major objectives of the proposed rule were to:

1. Permit the Department's Meat and Poultry Inspection Program to take advantage and make use of newer technology and plant QC systems.
2. Increase availability and reliance on objective information to augment the continued on-site inspection by the Department's food inspectors.
3. Streamline the regulatory process in line with Administration policies.
4. Shift some of the emphasis from inspection of end products to controls at critical points in the process where significant variation can occur that affects the end product.
5. Establish a base of experience to be drawn upon to assist in determining future directions for regulatory reform.

Development of Federal Meat and Poultry Procedures for Processed Products

In the early part of this century, Congress saw a need for a regulatory inspection program that would assure safe and wholesome meat and meat products for consumers and facilitate the marketing of such wholesome meat and meat products. Therefore, legislation was enacted and a program was developed based on the needs of the public at that time. Government inspectors were stationed at packinghouses to sort out and inspect certain livestock and carcasses and parts thereof. They were also responsible for inspecting the manufacture of processed products of such carcasses, even though there were relatively few products of this type (mainly, formulated sausages with relatively few ingredients). This regulatory inspection program proved to be very effective in fulfilling the statutory objectives. Every animal and its carcass and parts were inspected before and after slaughter (ante-mortem and post-mortem inspection, respectively, which is still performed today on every animal). Inspection also applied to operations involving

manufactured products even though every single piece of sausage or retail cut of meat was not individually inspected. Instead, the inspectors would supplement their examinations of samples of the products with examinations of the various manufacturing operations in the plant to make certain they were in order.

Transition Era

In the period immediately following the second world war, national economic growth, advanced technology, industry competition, and other social changes caused a significant evolution in the nature and type of meat and meat food products prepared and marketed. Each year more meat products reaching the consumer were composed of complex blends of ingredients—some of which were technologically synthesized.

During this time, however, the Government's regulatory techniques remained essentially unchanged. As additional inspectors were hired to meet industry growth, the inspection program began to rely more on laboratory analysis to confirm the wholesomeness of finished products. However, the laboratory analyses were used mainly as a check on the inspection program rather than as a tool for monitoring a meat plant's effectiveness in manufacturing products in compliance with the Government's requirements.

In the meantime, data indicated that public health problems from diseased animals were being well controlled. Industry, as well as the Government, was responsible for the disease-free and wholesome product reaching consumers. Meatpackers realized they could not survive at the expense of jeopardizing the public's health.

Modern Technology Era

In the 1950's the post-war trends intensified. There were rapidly growing scientific knowledge and technology, growth in population, expansion of market areas and development of international trade, keener competition, increasing production costs, and a growing consumer interest in consistent and uniform goods and services of all kinds, including meat and poultry products. Consumers came to expect, for example, that a package of a particular brand of hotdogs had the same basic characteristics of appearance, taste, aroma, and texture as the last package purchased. Marked changes began to appear in the meat and poultry industry. Firms began to modernize their plants, and many began to specialize in slaughtering, canning, manufacturing sausage, processing ham, etc.

With these developments, there was an apparent need for more effective production control mechanisms—in modern-day terminology generally called "process quality control." The term "quality control" (QC) is used as though it has a number of meanings. For example, it may be used in reference to controlling the appearance and taste of products or the finished products requirements, such as moisture content, or to controlling the production process. It more correctly should be used to refer to a method or system of controlling the quality of a process within certain specifications. By the sixties, some meat and poultry processors were designing QC systems specifically for controlling the production process, thereby providing a consistent and uniform product at a predicted cost, as well as one meeting Government regulatory requirements.

Thus, firms were no longer relying entirely on the Department's regulatory system as a product control mechanism and as a means of aiding equitable competition. They found that designing their own QC systems was cost effective as well as an efficient means of assuring compliance with the Department's regulatory requirements.

Status of the Department's Regulatory Efforts

Despite the dramatic changes in the meat and poultry industry, the basic techniques of inspection have remained essentially the same, as the various legislative changes had left the underlying inspection law virtually unchanged.¹ However, there has been an increasing need to rely on methods other than direct physical inspection of products in the face of industry growth (new plants requiring new inspectors), the vast number of new and highly complex products being developed, the advent of computerized formulation, the use of vegetable protein products, the growing stresses on Government laboratory capabilities resulting from the need to detect pesticide and drug residues, antibiotics and other potentially toxic substances, and increasing budget constraints.

During the past few years, the inspection program has been able to develop some new procedures that have increased inspector efficiency. These

¹In 1967, Congress enacted the Wholesome Meat Act (Pub. L. No. 90-201, 81 Stat. 584), which made a number of changes in the existing law, particularly regarding Federal-State relationships, but which substantially preserved the inspection requirements contained in Title I of the Federal Meat Inspection Act. One year later, the Poultry Products Inspection Act (Pub. L. 90-492, 82 Stat. 791) was similarly amended.

procedures primarily involve the use of statistical sampling. Reliable information can be obtained from samples to control the production process. Sampling schemes can be designed to provide a reliable method for determining whether the lot of finished product is wholesome and otherwise not adulterated and should be passed. For example, with a prescribed sample size from a given lot of battered and fried chicken, an inspector can determine that the lot of battered and fried chicken does not exceed the Government standard of 30 percent batter.

These statistically valid sampling and examination schemes have modified or supplemented many inspection procedures which relied heavily on sight, smell, and taste to determine if a product was wholesome and unadulterated. Moreover, these more objective schemes have minimized the inconsistencies and problems arising from the more subjective inspection approaches.

Synopsis of Quality Control (QC) Concept

With respect to this rulemaking, the concept of QC is to control the production process in order to provide for a consistent and uniform finished product at a predicted cost as well as to conserve resources. A complementary benefit is a way to assure compliance with the Department's inspection regulations. QC can be applied either to the entire food production system of the establishment (i.e., a total plant QC system) or limited to a specific process or product (i.e., partial QC program). In every production process (including meat and poultry production) certain kinds of variations will occur. Factors such as protein, fat, and moisture content, and texture, flavor and color are controllable within certain limits but differences do exist in the finished products. Decisions must be made concerning the limits for each factor. For example, a company may be producing hamburger which is to contain no more than 30 percent fat. A target level of less than 30 percent fat is set, followed by the development of sampling schedules and analytical limits. Then production methods and process control procedures are established to assure that the hamburger is within the 30 percent fat specification. The target level that is set will depend upon how closely the processor can control the production process. One processor might have to aim at 27 percent fat while another might aim at 29 percent because of differences in their abilities to control

the process. Both can meet the objective of no more than 30 percent fat.

Under a QC system, "on line" checks are made at key points in the production process. The points are significant in the sense that any unwarranted variation at such a point will generally result in the finished product not conforming to predetermined requirements. The information obtained at these points enables the processor to make adjustments or corrections to the process as necessary, generally long before output quality has been adversely affected. Even when this cannot be accomplished, it allows the processor to isolate the small portion of product that is affected in order not to jeopardize the whole lot.

In using such approaches and establishing targets, sampling plans, and limits, distinctions must be made between controllable and uncontrollable factors. The science of mathematical statistics provides the means to measure and deal with variability. In a production system, such as the one used in the manufacture of meat and poultry products, variations which are uncontrollable, natural, expected, and quantifiable will result in random fluctuations of sample results around some central point (which may also be the target). Knowing the uncontrollable variations and the extent of their fluctuation, a control chart can be designed and used to identify fluctuations due to controllable causes. Those causes can then be eliminated. Corrections can serve the many purposes discussed earlier in this document, namely assuring a consistent quality level, uniform product characteristics, production cost control, and avoidance of the risks of repercussions from the Department's regulatory mechanisms.

Since more and more establishments now use effective QC systems, there is tremendous potential for the Department to use the data and information generated by these systems in order to more efficiently and expeditiously carry out its inspection responsibilities with no loss in effectiveness.

Cost Savings To Be Achieved by Implementing the Quality Control Concept

The potential benefit of total plant quality control to the Department can be measured by expected gains in efficiency. The increase in efficiency can be viewed as either person-years of inspection gained or person-years of inspection avoided. The first represents the case where program growth (new plants requiring inspection) is static while the latter represents the ability to

assume the inspection responsibility for additional plants without additional cost.

The draft impact analysis contained projections of expected net benefits to the Department based on a number of assumptions. Included in these assumptions were efficiency gains of 30 and 60 percent in the assumed expected participation rates for various plant sizes. These assumptions were combined with information about average inspection person-years for each size group. The assumed participation was 100 medium to very large processing plants during a 5-year period; no participation was assumed from small or very small plants, those with annual production of 0.5 to 3.0 million pounds, and those with less than 0.5 million pounds, respectively. At the time, it was thought that small plants would not participate in total QC to any significant degree because of implementation costs and other difficulties. Further, since most small plants have traditionally been subject to "patrol" inspection (groups of small plants subject to a single inspection assignment for efficiency), they did not appear to offer much potential for further productivity gain.

Subsequent to the issuance of the proposal, the total QC approach was implemented in a cross-section of pilot plants, including small plants. The small pilot plant experience demonstrated the feasibility of providing departmental assistance for the implementation of total QC in small plants. Although experience is still very limited, it appears that a trained USDA processing specialist may be able to assist as many as 26 small plants per year.

The initial success of total QC in the pilot plant experience suggests that inspection efficiency, beyond that already achieved with patrol inspection, may be enhanced. This would be particularly true in situations where all plants in a given patrol participate in total QC.

Refining the assumed participation rate to include small plants is also reasonable and proper considering the significance of inspection program growth. As mentioned earlier, the prospects for expansion of workload are essentially related to the assumption (designation) of State inspection program responsibilities. Nearly all State inspected plants would fall into the small plant category and could represent a doubling in the number of such plants currently under Federal inspection. The significance of total QC as a means of cost avoidance is underscored by the possibility that designation of all the State inspection

program responsibilities could require an additional 800 Federal inspectors, even if only "patrol" inspection procedures were available to the Department. However, the total QC approach could likely provide enough increased efficiency to the Federal inspection program, particularly in view of the more long-run nature of prospective designation activity, to handle this potential program growth without increasing the inspection force as much as would be necessary without QC systems or programs. That could potentially represent \$15 million in annual cost avoidance.

Including small plants in the projections from the draft impact analysis seems appropriate now that pilot plant experience has been gained. Assuming that 10 percent of the small and very small plants participate (the rate for very large plants was 15 percent), the cumulative efficiency impact of total QC for inspection of these plants could range from 74 to 148 inspection person-years (30 and 60 percent efficiency) and represent a benefit of \$1.4 to \$2.7 million over the 5-year period. Similarly, the 5-year cumulative inspection benefits for medium to very large plants (as developed in the draft impact analysis) is estimated to range from 147 to 293 person-years representing \$2.7 to \$5.4 million in inspection benefits.

In summary, implementation of total quality control can represent potential efficiency gains of roughly \$4 to \$8 million over a 5-year period. Expressed alternatively, total QC could provide for a \$15 million annual cost avoidance potential if fully implemented in small plants in the absence of State inspection programs.

In addition to the above costs savings to the Department as a result of widespread implementation of QC, any costs incurred by participating plants are expected to be negligible when compared with expected total QC benefits. Although some participants may have to make expenditures for equipment and/or services to implement total QC, most of the expected early participants have already incurred those costs in establishing their own total QC systems. Those systems are expected to be readily adaptable to the requirements of this rule. For other plants, including small plants, the participation costs are minimal (the analyses of these costs are clarified in the final economic analysis for this rule, which may be obtained from the office identified previously herein).

Quality control is a profit-oriented management tool. It provides the information necessary to consistently

produce a uniform, quality product at least cost. This action allows the information generated by that management tool to be used by inspectors to verify compliance with inspection requirements and reduces the plant's risk of incurring unnecessarily high costs caused by undetected process failures and subsequent Department compliance actions. A properly designed total QC system minimizes the occurrence of a process failure, indicates a failure without delay, and provides the information needed to quickly locate and correct the cause of the failure. A total QC system benefits the plant by reducing the risk of production delays, the need to reprocess and/or relabel large volumes of product and the likelihood of product recall and condemnation.

Quality control has already played an important role in the success of large national processors. These processors are heavily dependent on QC for the proper control of products produced at their typically large and complex plants. QC has enabled them to target production costs closely, thereby overcoming the marketing cost obstacles presented by national distribution, and to establish a competitive market price. To the extent that this action further enhances QC, it can also have an enhancing effect on the profitability and competitive position of those plants in comparison with those without QC.

Options Considered

Several options were considered before proceeding with the final rule.

Option 1 would continue the current Federal inspection program utilizing voluntary "partial" quality control programs for plants wishing to participate in such programs. This option would not provide for the efficiency gains possible with a total plant quality control approach.

Option 2 would permit implementation of a total plant voluntary quality control system in processing plants as an adjunct to traditional inspection methods. This allows an inspector to utilize a plant's quality control records, together with regular inspection checks and tests, to determine compliance with Federal meat and poultry inspection regulations. Current legislation permits such an option.

Option 3 would adopt a mandatory total plant quality control system. However, a voluntary total quality control system cannot be converted to a mandatory program without enabling legislation and there are no present plans to seek such legislation.

Option 2 was selected for the reasons stated herein.

Comments

The Department received a total of 1,550 written comments from interested individuals and organizations. The comments were divided into the following categories along with the number received:

1. Individuals.....	1,416
2. USDA Inspectors.....	64
3. Members of a Union Affiliated with the American Federation of Government Employees (AFGE).....	25
4. Private Industry Representatives.....	20
5. Industry Trade Associations.....	9
6. Individuals Affiliated with Universities.....	4
7. Members of Congress.....	3
8. State Government Representatives.....	3
9. Employees of Processing Plants.....	2
10. Unions or Associations not Affiliated with AFGE..	2
11. Consumer Organizations.....	2

Of the 1,416 comments from individuals, 1,135 were submitted on one of six form letters bearing a total of 5,180 signatures.

Fourteen comments were considered generally positive toward the proposal by suggesting that the concept is sound and necessary, and that it will allow the regulatory policies and procedures to keep abreast with technology. Some contained suggestions or made other points which were also raised by other commenters and which are identified and discussed below.

Twelve comments were considered neither positive nor negative. They discussed advantages and disadvantages of quality control in general without specifically addressing the merits of the proposal.

On January 16, 1980, the objectives of the proposal and comments received from the public were discussed with the Secretary's National Advisory Committee on Meat and Poultry Inspection. The Committee is comprised of representatives from the scientific community, State governments, industry, and consumer groups. Although the Committee did not make a specific recommendation, the Administrator of FSQS viewed the individual comments as beneficial and encouraging.²

The remaining comments were considered negative toward the proposal and raised a number of issues identified and discussed below:

1. *Freedom of Information.* During the comment period, 16 comments from industry and from persons affiliated with universities expressed concern that

² A transcript of the Committee's views is available for public review in the office of the Regulations Coordination Division, Room 2637, South Agriculture Building, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250.

the written QC plans and procedures submitted by participating plants would be subject to disclosure, in whole or in part, pursuant to requests under the Freedom of Information Act (FOIA), 5 U.S.C. 552. Moreover, the same concern was voiced by some of the plants initially volunteering to participate in the Agency's pilot plant test studies which began November 5, 1979, and are still continuing in some plants.

The primary purpose of the FOIA is to facilitate release of information contained in government records. However, recognizing that release of certain information requested could cause potential harm to businesses and individuals, FOIA exempts particular commercial and financial information from mandatory release by government agencies. See 5 U.S.C. 552 (b)(4). Much of the material submitted by participative plants would appear to come within this exemption.

It should be noted at the outset that certain information and material about a plant's QC system may exist but would not need to be submitted to the Administrator of FSQS for review and evaluation as a part of the application and approval process. These include intra-plant, intra-company, and intra-corporate QC instructions to employees, position descriptions, data and information relating to customer complaints, specific laboratory methods, information on quality cost programs, quality cost improvement programs, any annual quality plan, and records of audits of the QC system done by an independent consultant or firm.

The material that must be submitted to the Administrator of FSQS by a plant seeking approval of its QC system includes, but is not limited to: recipes for product; specific methods, tests and procedures to examine and control raw materials; in-process critical tests, observations and evaluations; finished product critical tests; finished product specifications; sanitation specifications; sampling plans, including size, frequencies, targets, tolerances, and limits; methods for verifying certain labeling claims (such as "Declared Count"); employee training programs; equipment calibration program; and control charts, graphs, and data.

The material submitted is not standard for each company, but varies because of differences in the nature and cost of such things as raw materials, methods of preparation, variations unique to the equipment, finished product specifications, and overall manufacturing costs.

Quality control systems operated by individual businesses are ultimately for the purpose of maximizing profitability

while maintaining product quality in keeping with company policy and requirements, and may also satisfy regulatory requirements. Thus each and every aspect of a company's quality control system in some manner relates to costs and profits. Quality control departments and/or individuals in these companies must show their management the nature and extent of the financial benefits of the QC system. If such information were released under an FOIA request, the nature and degree of a processor's vulnerability to competition could be determined. This could be possible even to a point of knowing whether or not the reason for the vulnerability is due to such things as the inability to obtain the right type of raw materials, because of costs related to equipment, labor, energy, and transportation.

Therefore, the Department's view is that although each request for information under the FOIA will be considered separately, most material required to be submitted to FSQS under the voluntary meat and poultry plant QC system would include trade secrets or confidential commercial or financial information which is privileged or confidential and therefore exempt from mandatory disclosure under the FOIA.

In recognition of the importance of this matter, however, the Department has considered the possibility of returning all copies of material concerning a plant's QC system to the plant or its designated representative after review and approval. Under either arrangement, the material concerning a plant's QC system would have to be readily available and accessible to the Administrator of FSQS or his designee at all times.

It appears that such options are possible but very impracticable for either FSQS or the plant for at least two reasons. First, the FSQS staff personnel at headquarters or regional offices frequently receive telephone inquiries concerning problems or other matters of significance about a particular QC system or program. In the overwhelming majority of cases, such calls cannot be responded to until the staff person receiving the call refers to a copy of the material concerning a plant's approved QC system. If a copy of such material were not on file in the headquarters or regional office, these calls could not be responded to until a copy of the material was made available. This could be cumbersome and time consuming, and in some cases could cause retention of product or even cessation of production until an answer to the inquiry was provided. In any case, this would not

appear to serve the plant or the Agency's interest.

A second concern is that of maintaining the integrity of the QC system. Since the Department would not possess a copy, a system would be necessary to prevent the substitution of pages that had not been previously approved by the Administrator of FSQS. Such a system would be time consuming and expensive to operate, and would likely cause communication problems when updating or revising of the system is attempted.

In view of the above, the Department has determined that at the present time it would not adopt a policy that would allow maintaining copies of material concerning a plant's QC system only at the plant or with a designated representative.

With respect to this overall issue, the Department has determined that information submitted by plants in connection with this regulation includes trade secrets or confidential commercial or financial information which is privileged or confidential and therefore exempt from mandatory disclosure under the FOIA. Moreover, release of any such information would inhibit plants from voluntarily participating in a QC program.

2. Mandatory Quality Control. The possibility of this voluntary QC rulemaking eventually being made mandatory was expressed as a concern in 14 comments including those from industry, trade organizations and the North Carolina Department of Agriculture.

The Department is committed to continually evaluating all methods used in carrying out its inspection responsibilities. Some changes, such as the way poultry slaughter inspection is conducted, which have recently been instituted, result in substantial manpower savings to the Department with no loss in effectiveness of inspection. While the commitment to find new and better ways to conduct inspection exists, the voluntary total plant QC system cannot be converted to a mandatory program without amending the present Federal Meat Inspection Act and Poultry Products Inspection Act, respectively.

The General Accounting Office report, *A Better Way for the Department of Agriculture to Inspect Meat and Poultry Processing Plants*, dated December 9, 1977, did recommend that the Secretary seek legislative authority to require mandatory total plant QC. The Department has considered that recommendation but has determined to hold in abeyance any immediate effort to seek amendments to the existing Acts

to provide authority requiring mandatory total plant QC systems. This decision is based upon the Department's knowledge of and experience with the industry; the experience of the Department in fulfilling the obligations under the Acts designed to assure that meat and poultry products are safe, wholesome and truthfully labeled; and the limits of the data currently available on the operation of total plant QC systems.

3. *Labeling Logo.* The proposal would have allowed the use of a logo or symbol on the labeling of products to indicate that the products were produced by a plant operating under a QC system approved by the Administrator of FSQS. There were 137 comments expressing concern about the use of the logo. They spanned most groups of interested parties responding to the proposal, including individual consumers, FSQS food inspectors, the inspector's union, industry, trade organizations, persons affiliated with industry, and consumer groups. Some individual consumers as well as people affiliated with universities were concerned because they appeared to misunderstand the proposed use of the logo, in that they believed that the logo would be used in lieu of the requisite inspection legend which states "U.S. Inspected and Passed" or "Inspected for Wholesomeness by U.S."

Industry commenters opposed use of the logo on two bases. First, there was the argument that a logo would not have the prestige of the requisite inspection legend; and second, that the meaning a logo would have to consumers could be discriminatory to those plants not desiring to participate in a total QC system and therefore not entitled to use the logo. Most industry commenters generally expressed the opinion that the logo could be misinterpreted as an indication of superior product quality and that as such it would be untruthful and confusing to consumers.

Whether or not the logo would gain the acceptance and respect enjoyed by the inspection legend would depend on the success of the QC system and the public's understanding of it. Whether or not the use of two separate official USDA marks or devices would confuse consumers appears to be conjecture. However, the Department is aware that some consumers do not understand the distinction between other markings which are currently used by the Department, such as the meat quality grade marking "U.S. Choice," and the Federal inspection mark "U.S. Inspected and Passed." Over the years, the Department has continued to offer

information and education programs to promote understanding of its programs. Those efforts will continue.

However, the labeling logo was proposed with the expectation that establishments with FSQS approved total plant QC systems would desire to communicate that fact to their customers.

Under the Federal meat and poultry products inspection Acts and the regulations thereunder, establishments participating in the QC program would be permitted to advise consumers of their products of such participation through some form of labeling technique or logo, as long as it is not false and misleading.

The Department believes that the proliferation of company devised labeling techniques or logos would be confusing to consumers, and further, that any Department-sponsored education program would be ineffective to eliminate such confusion.

Therefore, the Department believes that a standard QC logo is not only appropriate, but necessary to avoid confusion among consumers concerning the products being purchased. It should be emphasized, however, that the logo itself is not required to be used, but may be voluntarily used by participating companies.

Therefore, after considering this matter and the factors previously discussed, the Department has determined to retain the proposed provisions for the labeling logo.

4. *Terminology.* Six comments questioned the appropriateness of the terminology "quality control" in connection with the proposed rule. These comments were from consumer groups, the FSQS food inspector's union, and trade organizations.

There have been a number of terms used in the development of more formal and systematic controls for manufacturing in general. However, during this developmental period the term most commonly used in everyday conversation, in technical conferences, and in literature, sales and marketing information has been "quality control."

The Department's evaluation and understanding is that the proposed term has two major meanings within the discipline. First, it is used to refer to the relative attributes or characteristics of a product. Second, it is used in referring to the effectiveness of control over a production process to assure uniformity and predictability of the characteristics of a finished product.

An example of the first meaning might be a particular brand and type of ham which possess qualities thought of by the consumer as being desirable, such as

the amount of waste (if any), the amount of connective tissue present, the color and texture of the meat, and so forth. An example of the second meaning could be the degree of control in manufacturing the ham to assure that the same muscles are always used in the right proportions, that the muscles are always trimmed the same way, that the connective tissue is adequately removed, that the curing solution added is carefully controlled to assure proper preservation and uniform appearance of the finished product, that the cooking process assures product finished to the same degree of doneness, and the chilling and packaging procedures do not vary so that surface dehydration or color deterioration is not excessive. These factors, and others, must be controlled so that there are minimal differences from ham to ham and lot to lot, in order to build customer confidence that the product is always the same.

Therefore, these two major meanings of "quality control" are generally recognized and accepted in academia, by the American Society for Quality Control and its members, and in the industrial arena. Even though "quality control" is the more universally used and accepted terminology, other terms are used in industry, such as "Product Performance," "Product Integrity," "Quality Assurance" and "Process Control."

Some companies or individuals make distinctions between "quality control" and "quality assurance." In such cases, the prior term is usually used to refer to the actual in-plant control of a manufacturing process while the latter usually refers to an auditing function that assures the in-plant control is functioning effectively. In other situations the terms quality control and quality assurance are used interchangeably.

Under the circumstances, the Department has determined that the importance of the terminology used is related to the clarity of meaning and purpose. The term "quality control," as used in connection with this rule, refers only to the effectiveness of manufacturing controls and assurance that products are not adulterated or misbranded (that is, the second meaning and example cited above). Thus, the term "quality control" is retained in this rule.

5. *Continuous Inspection.* Acknowledged and discussed in the preamble to the proposal was a question of whether or not the proposed changes in inspection methods would be an abdication of the Secretary's responsibilities under the Federal Meat Inspection Act (FMIA) and the Poultry

Products Inspection Act (PPIA). Section 6 of the FMIA (21 U.S.C. 606) provides in part that " * * * the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment * * * and said inspectors shall mark, stamp, tag or label as 'Inspected and passed' all such products found to be not adulterated; and said inspectors shall label, mark, stamp, or tag as 'Inspected and condemned' all such products found adulterated * * *."

A narrow interpretation of the above language could mean that a departmental inspector must personally and literally inspect (by some method which the Act does not prescribe) every frankfurter, package of luncheon meat, pork chop, etc., before it could bear the "Inspected and Passed" wording, and further that a departmental inspector must personally and literally place every label, mark, stamp, or tag on each such item. This language has not been so narrowly interpreted in the administration of the Act. To the contrary, the Department has exercised some discretion regarding its methods of inspection, particularly with regard to processed products with complex formulations. The Department has adhered, however, to the principle that Federal inspectors make the determinations as to which products are adulterated and misbranded and which are not, and that the marks of Federal inspection are placed on the products by the inspectors or by establishment employees under that degree of supervision by the inspectors necessary to assure the marks are properly applied only to products eligible therefor.

Similar provisions regarding inspection are contained in section 6 of the PPIA, although the Secretary has slightly more discretion under this Act with respect to the extent of inspection of "further processing" of poultry products than he has under the FMIA with respect to meat food products.

There were 392 comments that indicated that the proposed rules could not be considered continuous inspection as prescribed in the cited provisions of the Federal Meat Inspection Act and Poultry Products Inspection Act. The comments came from individuals, FSQS food inspectors and the inspector's union.

The Department has again carefully evaluated this matter. It is important to reiterate to consumers of meat and poultry products that this rule does not reduce the Department's authority and responsibility under continuous

inspection, or the authority and responsibility of the Department's inspector to carry out inspection requirements. It does not reduce the Department's authority and responsibility to remove adulterated or misbranded product from the food chain or to deal with any unscrupulous operator.

6. *Reopening the "comment period"*. Since publishing the proposed rulemaking, the Food Safety and Quality Service of the Department has been engaged in testing total plant quality control concepts on a pilot basis in certain cooperating plants. As of July 1, 1980, those who have or are cooperating include: Peter Eckrich Company, Chicago, Illinois; The Kroger Company, Salem, Virginia; Saluto Foods, Montgomery, Alabama; Tyson's Foods, Monnett, Missouri; Safeway Stores, Stockton, California; S. Clyde Weaver, East Petersburg, Pennsylvania; Edwards Sausage Company, Lawrenceburg, Kentucky; Berks Packing Company, Reading, Pennsylvania; Portion Control Foods, Mansfield, Texas; Equity Meat Corp., North Baltimore, Ohio; Von's Grocery Company, El Monte, California. Others indicating a definite interest include: Armour Foods, Fort Madison, Iowa; Cudahy Co., Denver, Colorado; and Rudy's Farm Company, Florence, Alabama. Eight comments from industry representatives requested that the comment period on the proposal be reopened after all the plant studies have been completed.

The objectives of the plant studies are to:

- a. Determine the extent of industry interest.
- b. Identify and evaluate the nature of industry concerns.
- c. Refine the specifics actually needed in a written QC system.
- d. Provide additional experience in preparing audits of inspection procedures for FSQS personnel.
- e. Gain greater insight into the degree of inspection efficiency than was available.
- f. Gain deeper insight into the nature and extent of training necessary for FSQS food inspectors.
- g. Develop the logistics and a regimentation for evaluating, approving, implementing and monitoring total plant quality control systems.

As the above indicates, the objectives of the plant studies relate to the most effective and efficient means of establishing and maintaining a program, and not to adding new information relating to the suitability of the QC concept. Thus, the Department need not delay this rulemaking until the

completion of the studies to determine the appropriate substance of a final rule.

7. *Less Consumer Protection*. Some 144 comments, including those from individual consumers, consumer groups, FSQS food inspectors, and the inspector's union expressed concern about a possible reduction in consumer protection. The comments also expressed views that the consumer would be better served and tax money better spent by increasing the current FSQS inspection force and remaining with the current "on-site" inspection. It was also suggested that Federal inspection personnel must maintain full authority over all phases of inspection with full authority to retain, reject or condemn any quantity of product, facilities or equipment which is deficient or not satisfactory. Many of these comments offered the view that the adoption of the quality control concept would not provide the consumer with the clean, healthful and unadulterated meat product to which said consumer has become accustomed.

A crucial concern of the Department is that consumer protection not be lowered or jeopardized by the quality control program. The Department intends to ensure that such a consequence will not occur. In plants volunteering for the program, all data and information generated by the plant's quality control system will be available to the Department's inspection personnel pursuant to the establishment's approved QC system. Thus, the Department's food inspectors will actually have additional information available for use in carrying out the inspection responsibilities of assuring consumers safe, wholesome and truthfully labeled products. Since this additional data and information will now be available to the inspectors, they will no longer need to personally generate as much data and information as is now necessary. Thus, there exists the potential for increased efficiency in inspection resources for the Department.

Based on the Department's knowledge and experience with partial quality control programs, the experience of the test plant studies, and the experiences of other government agencies with the quality control concept, the Department believes that this voluntary quality control program will be more efficient than the present system of processing inspection, with no lowering of consumer protection.

8. *Recordkeeping*. One attribute of a QC system is the records maintained by the plant and their availability. These records will show the nature and type of checks done at various critical control points throughout the process, the

findings of those checks, and other complementary material—such as charts and graphs. The scope and intent of such records will vary significantly from plant to plant based on numerous variables such as size of plant, number of employees, types of products, type of equipment and its capability, and the volume of production. The proposed rule did not specify the scope and extent of records that would be needed for voluntary participation in the quality control program.

Ten comments from FSQS food inspectors and the industry expressed concern that recordkeeping requirements could be excessive, burdensome and costly. The Department acknowledges that such an inference could be drawn. As indicated above, however, while some recordkeeping will be necessary to ensure the continuing effectiveness of a plant's QC system, the Department will not insist on recordkeeping in a QC system beyond that necessary to demonstrate the effective administration of that system. In some cases, the usual records may be adequate. In others, modification of existing records or additional records may be needed. However, such records will most likely be as beneficial to the plant's management as to the Department. In accordance therewith, the provisions concerning recordkeeping contained in the final rule have been clarified to assure that the records agreed to be available to Department personnel under the QC system will be maintained to enable the Department to monitor compliance.

9. Uniform Approval and Administration. Three comments were received from industry which expressed concern that a decentralized system of reviewing, approving and administering the quality control program could lead to inconsistent and conflicting policies and procedures. This, the comments indicated, would confuse and frustrate the industry, and would make it extremely difficult for the larger processors to operate in multiple regions and areas. The Department recognized this as a potential matter of interest to the industry and discussed it in the preamble of the proposed regulation.

While eventual decentralization to the regional level for handling some aspects of the program could occur, the Department is initially committed to central control. Any decentralization will be considered only after suitable guidelines and criteria have been developed and a suitable audit system has been devised to assure a sound, uniform and consistent manner for

reviewing, approving, administering, and auditing the QC systems.

10. New product test-marketing. It is common in the industry to test market new products on a limited scale and in carefully selected locations before company commitments are made to go into full scale manufacturing and broad-based marketing. In most cases, modifications in the product and/or process occur as a result of the test-marketing data and experience. Also, in some cases, company commitments necessitate the purchase and installation of expensive equipment, and even in a few cases the expansion or modification of existing buildings, or erecting new structures. In many other cases, decisions are made to shelve a product after the test-marketing.

The intent of the Department's proposed rule was that a formal quality control system be approved for all phases of the processing, for all products in a plant, and for all supporting functions, such as sanitation, pest control, and so forth.

A trade organization in one comment raised the question of how new experimental products could be test-marketed if a detailed quality control procedure must be approved even though the product and production process may have not been finalized.

Many parts of a plant's QC system are general, such as sanitation, pest control, employee welfare and training, and maintenance of the facilities. Even for new product development, all of these parts of a manufacturing plant's support system would remain intact and functional. In view of this, and recognizing that modifications may be required in the development of a new product, the Department agrees that a special procedure should be provided for such cases. The final rule, published hereafter, contains provisions permitting (with certain limitations) the manufacture of a new product for up to 6 months in a plant for which total quality control has been approved.

Although a product is new, the processor must still determine the objectives for any particular test production run. The objectives will include a formula for the new product, a processing procedure, and what the key points will be for controlling production runs to assure the product meets specifications. This information is conveyed to plant employees responsible for conducting the production runs. The same information could be provided the Department's food inspector.

In view of the special need, provision is made for the processor to convey the information to the Department's

inspector prior to initiating production runs. If the inspector determines that labeling for the new product has been approved by the appropriate officials of FSQS, and that the method for controlling the production runs will assure that the product meets all Federal requirements, he may allow production of new products (not reformulation of old ones) for test-marketing for up to 6 months. By the end of the 6-month period, the processor must have a quality control procedure approved by the Administrator in order to continue production of the new product under a total QC system.

The Department believes the procedure will provide adequate flexibility to the processor for the production and test marketing of new products, while affording the public and the Department the benefits and the protection provided by the QC system.

11. Reduce inspection overtime and upgrading quality of inspection. Under current laws and policies, the cost of Federal mandatory inspection of meat and meat food products and poultry and poultry products is required to be borne by the United States, except the cost for overtime and holiday work. Many plants work more than 8 hours per shift, and others conduct some operations requiring inspection during holidays. In these cases, FSQS bills the plant for reimbursement at the current rate of \$15.44 per hour of additional inspection service rendered. An approximate average annual cost for a processing plant is \$3,000 per year, with some plants paying as much as \$48,000 per year.

With respect to the above, and because there are some industry concerns about the quality of inspection rendered, the Department received six comments from industry personnel stating that the charges for this additional inspection time should be reduced or eliminated—coupled with more efficient use of the Department's food inspectors—and that the quality of inspection rendered should be upgraded.

One of the goals of the total plant quality control program is to improve efficiency of inspectional resources—including use of personnel. The Department recognizes that achieving efficiencies could be slow initially, but will be realized as experience is gained. To the extent that a QC system or program does make inspection more efficient, there may be a reduction in the amount of overtime work required. However, since inspection is required by law and plants receiving overtime inspection must bear the costs of overtime work, if overtime is needed,

those costs to inspected plants cannot be eliminated.

The Department believes that any shortcomings in the quality of inspection that might now exist can be improved with the development of this QC program, and with training and education, experience, good communications between the Agency and industry, and finally with effective supervision.

12. Impact on small business. Some 23 comments from trade organizations and academia expressed concern about the impact of this program on small business. Some commenters indicated a fear they would be "squeezed out." Other commenters stated that the need to designate a plant employee as responsible for QC records and the sampling and testing of products would present serious problems to small plants with limited numbers of employees. In addition, inquiry was made about the Department's definition of "small business."

The principles and procedures for QC are as applicable and beneficial to small processors as to large ones. In many cases, QC systems in small plants can be more efficiently administered due to more simple organization structures and more direct means of communicating.

Moreover, contrary to the impression that some people have that the term "quality control" requires highly trained technicians working in expensive laboratories, a plant QC system can be rather simple and inexpensive, and still be effective.

The Department is aware that, in many cases, the small processor does not have the variety of raw materials or production options available to the large processor, must rely on product quality, production costs, and in some cases distribution advantages in order to effectively compete, and cannot afford the expensive laboratory equipment and professional quality control staff which many large processors use with their "in process" controls. However, any measurements necessary in the operation of a QC system can be made by regular plant employees with relatively little training. Moreover, inexpensive analytical equipment is available and can be operated by the regular employees. Use of such equipment is usually fast, economical, and adequate for the purpose. Suppliers to the meat and poultry industry, particularly those engaged in selling non-meat and non-poultry ingredients such as spices and flavorings, often make analytical help available as well.

In developing this rule, the Department has recognized the need to consider its impact and effect on the

small processor. In the past, the Department has assisted many small processors in implementing microbiological monitoring of their sanitation programs without employing a microbiologist; determining fat and moisture content of frankfurters and bologna without expensive laboratory equipment or chemists; and controlling the count of product units in a container by periodic samples and charting results. In testing total plant QC in one very small plant, the Department provided direct assistance in doing an analysis of the plant operations, identifying and recommending techniques that could be employed by the plant, preparing the written QC system, and implementing that system. The Department will provide the same type of assistance to small processors in the future to assure they will not be squeezed out.

Moreover, a Small Plant QC Guidebook is being prepared and will be ready for distribution shortly. Using the Guidebook with a minimal amount of further assistance, a plant owner or operator could develop the basic framework of a total plant QC system. Copies of the Guidebook may be requested now, for mailing as soon as it is finished, from the FSQS Information and Legislative Services Division, Outreach Branch, U.S. Department of Agriculture, Washington, D.C. 20250.

It should be noted that small plants already have some sort of "control" program. While it may not be formal, in most cases, it will require only minimal effort to comply with requirements for the Department's approval. Entering into the voluntary total plant quality control program may mean an additional expense to the plant. However, as noted above, this expense will be minimal and will vary depending on how elaborate or refined the plant desires the QC system to be. In any case, the program is strictly voluntary.

The Department has not formally defined "small business" with respect to this rulemaking, except for the purpose of doing an economic impact analysis. That definition included plants producing 3 million pounds or less of product per year. The definition of a small business used by the Small Business Administration is one with 500 or fewer employees. Neither definition would seem appropriate for this program.

Rather than define the term "small business" for this regulation, the Department has determined that it will provide assistance to all plants requesting it to the extent resources allow. This will be in keeping with the commitment that small processors will

not be injured because they did not understand the Department's policy and requirements for a quality control system.

13. Concern with plant records unrelated to health, safety, and labeling matters. One comment from industry raised the issue, which is related to one earlier discussed, of the meaning of the terminology "quality control." The commenter was concerned that the Department would regulate nutritional quality and sensory factors such as taste, aroma, appearance, and size by establishing specific requirements for specific products. That is not the objective of the proposed quality control program. The purpose for submission of a total plant QC system for the Department's approval is to provide a basis to determine how and to what extent the QC system meets regulatory requirements, and provide insight into the scope of the plant's methods, procedures, and specifications. The Department would not require, for example, that information relating to sensory or nutritional quality factors be included in a QC system except in cases where product covered by the program bears labeling claims of nutrient content.

14. Business capriciously damaged. Three comments from academia expressed concern about the likelihood of business reputations being capriciously damaged or plants being shut down due to unusual human error or political motivation.

The principal source of this concern seemed to have emanated from the provisions in the proposed regulation outlining circumstances under which approval of a plant's QC system or program could be terminated. It is true that approval of a plant's QC system or programs will have to be terminated if the plant fails to effectively administer the system. It is also true that no matter how good and just the reasons, there could be disagreements between the Department and the plant concerning the adequacy of the basis for any termination.

The proposal addressed this matter and prescribed procedures for withdrawing approval of a total QC system or partial QC program. Terminating approval does not mean that the official grant of inspection will also be automatically withdrawn. In addition, procedures prescribed for terminating approval of the plant's QC system or program will include an opportunity for a hearing, upon request, in those instances where there is a conflict as to the facts concerning the adequacy of the basis for any termination. The Department, therefore,

concludes that the procedures provide the establishment with adequate opportunity to present its view in such matters and that the safeguards against defamation are reasonable.

15. *Expedient and efficient procedures for terminating approval of a quality control system or program.* One comment from the American Federation of Government Employees (AFGE) indicated that the procedures in the proposal for terminating approval of a plant's QC system or program were too cumbersome and time consuming, and could jeopardize consumer protection.

The proposal provided two provisions for terminating approval. Both are retained in this final rule. First, in the event adulterated or misbranded product is found by the Administrator to be distributed in commerce, approval may be *immediately terminated* pending final disposition of the matter after opportunity for a hearing on any disputed issue of fact. In the Department's view, this procedure is expedient and efficient while assuring a reasonable degree of fairness by providing for redress. Additionally, the Department believes that this basis for terminating approval should necessarily be extended to those situations where it is determined that adulterated or misbranded product is found to have been prepared for commerce, even though the product has not yet been distributed in commerce. The final rule, therefore, provides for termination of approval in the event that adulterated or misbranded product is *either* prepared for or distributed in commerce.

The second provision establishes a procedure to be used in the event problems arise in the effectiveness of the plant's QC system or program and inadequate correction of problems occur (adulteration or misbranding not involved). In such cases, the owner or operator of the establishment will receive a letter from the Administrator of FSQS or his designee, identifying the ineffectiveness and/or problems and giving the owner or operator 30 days to remedy them. If after 30 days the ineffectiveness and/or problems are not remedied, approval will be terminated. Since adulteration or misbranding is not involved, the Department has concluded that more stringent actions are not immediately necessary and that allowing a plant the opportunity to improve its performance under its QC system or program will not jeopardize the consuming public.

16. *"Approved list" of plants.* The proposal indicated that upon approval and implementation of a plant's total QC system, press information would be released identifying the plant's name

and location. In addition, the proposal stated that a current list of plants having approved QC systems would be maintained and available to the public.

One comment expressed the concern that plants not having approved QC systems, or having had such approval and later having had it terminated, could cause those plants to be looked upon unfavorably by present or potential customers.

Developing and operating an effective total plant QC system is newsworthy and the public has a right to be advised. Issuing press information serves that purpose. Maintaining a list of plants having approved total plant QC systems and making it available to the public will also serve the same purpose. Moreover, if information concerning the names of plants having approved total plant QC systems were requested under the FOIA, the Department would have to release such information. Consequently, a list of names of approved QC plants and their locations will be developed and made available to the public.

17. *Accurate economic impact analysis.* Five comments challenged the accuracy of the draft economic impact analysis done in connection with the proposal. These originated with the FSQS food inspectors' union, consumer groups and the industry.

The presentation of information in the draft impact analysis concerning the costs that might be incurred by a plant (in the footnotes of the tables rather than the text) apparently confused several commenters. The draft impact analysis was based on an estimate that 100 small plants would be in the program at the end of 5 years, and an estimate that the total additional costs to small plants would be approximately \$15,000 over that period. Thus, \$15,000 divided by 100 plants is \$150, and that divided by 5 years is \$30. Such proration did leave open the opportunity to draw an incorrect inference that the total cost for one plant would only be \$30. The Department's best estimate for one plant is \$1,600. That is, the estimated initial cost of \$1,000 plus \$150 per year maintenance cost. This matter is being clarified in the Final Impact Analysis prepared in connection with this final rule.

18. *QC may increase the total cost to the national food system.* Twelve comments from consumers, consumer groups, the American Federation of Government Employees, members of academia and trade organizations stated that the Department should not adopt the proposed rule solely to reduce tax expenditures if there is an equal or greater expenditure of monies by business (and ultimately consumers) to

comply with its provisions. Moreover, the commenters indicated that since the economic impact analysis done in connection with the proposal did not evaluate the economics from this scope, there should be an economic impact study to determine its potential or expected cost or savings to the consumer, the industry, the food inspector's union, and the Department of Agriculture.

The primary goal of the voluntary total plant quality control program is not to reduce expenditures but to improve efficiency at the current level of funding and in furthering regulatory reform. The program is voluntary and would not be adopted by a plant if its costs outweighed its benefits. However, the Department is aware of a number of companies that have effective total plant QC systems, and will maintain them for their own benefit. In most cases, these companies also incorporate procedures to assure compliance with regulatory requirements. The Final Impact Analysis indicates the economic impact to industry should be minimal. Therefore, it follows that there would be minimal increased consumer costs that would result from the adoption of the voluntary total plant quality control program.

19. *Lack of formal guidelines for inspectors.* One comment from a Department food inspector indicated that inspectors need well defined and published standards or guidelines in order to monitor all aspects of the total plant QC system; and that until these are provided, QC systems cannot be adequately evaluated.

There are a number of ways the Department intends to deal with these concerns. First, in participating plants, specific instructions will be developed for inspectors to use in carrying out their inspection responsibilities. Second, each FSQS Meat and Poultry Inspection Regional Office has competent staff personnel who will evaluate the operations of plants. Third, as discussed earlier in this preamble, the Department has developed a training program for its inspectors and supervisors who would be responsible for plants having approved total plant QC systems. The training program takes into consideration the principles of quality control, as well as a number of technical subjects such as principles of food microbiology. Its development involved extensive discussions and evaluations by the scientists and key Department administrative officials. Moreover, the Department's expert consultant—hired to conduct quality control seminars for the Department's technical specialists—

participated extensively in the design of the training program for inspectors and supervisors. As the program develops, modifications will be made as necessary. The Department believes these measures are more than adequate to initiate and administer the program.

20. Availability of plant representative. The wording in the proposed regulation that an establishment person must be available to the Department's food inspector for consultation "at all times" was of concern to one trade association.

The intent of the wording was to alert the industry that one person must be responsible for a plant's overall QC system. That person must be available to the inspector for consultation in the event the inspector encounters some unexpected but serious problem in the plant, or is encountering difficulty in understanding a lack of administration of the QC system by plant personnel, or finds it necessary to question any change in plant practices or procedures.

The implication of the comment was that food inspectors might find a need to call the "responsible person" out of bed at night, or on weekends, holidays, etc., when plant manufacturing was not occurring. The Department does not believe that FSQS food inspectors would act in such a manner, but if one did, first line supervisors would intervene. However, in order to assure that a responsible plant official is available in multishift operations, the plant owner or operator should designate a "responsible person" for each shift.

21. Qualifications of personnel. Two comments expressed the belief that the qualifications of the Department's food inspectors and supervisors should be equivalent to those of their industry counterparts; and that the redefinition of the food inspectors responsibilities and its effect on General Schedule (GS) rating and pay scale must be addressed.

The Department's information indicates that overall its inspection personnel are on par with those in industry, and believes the inspection personnel are competent and capable. The Department recognizes, however, that special knowledge and skills will be needed in connection with the QC program, and as previously discussed, special training will be provided to inspectors and supervisors assigned to plants with total plant QC systems.

22. "De facto" partner with industry. One comment from a trade association raised the question of whether or not a Federal regulatory agency could serve as a "de facto partner" in quality control for hundreds of plants across the Nation

and yet render timely, flexible and cost-effective decisions.

One of several capabilities of a plant's QC system is to satisfy regulatory requirements. The Department's inspection responsibility is to be sure that legal requirements are met. There appears to be no conflict of interest in such a relationship between the Department and industry. Both can benefit. Under such arrangement, the Department will not be any less able to render timely, flexible and cost-effective decisions, but can in fact improve in those areas.

23. Endless testing. One commenter expressed concern that FSQS could insist on large testing efforts in order for a plant to gain approval for its QC system, and then subsequently decide that such testing should be maintained long beyond the time necessary to achieve the purpose for which it was originally needed.

It is true that in cases where there is doubt or question, plants interested in the total quality control system could be requested to submit data demonstrating that the quality control procedures are effective. Beyond that, any good QC system will generate sufficient data to demonstrate that things are in "control," and that the Department's regulatory requirements are being met. Under these circumstances, the generation of data would not be necessary.

24. Food inspector support. Two commenters alleged that Department food inspector support for the total plant quality control system was minimal, and recommended that further support be developed since the success of the program depended in large part upon the attitude and cooperation of those in-plant inspectors.

Also, in these two comments there appeared to be concern about the potential for retaliatory action by food inspectors against plants contemplating or in fact participating in the quality control program. The Department believes that such consequences are unlikely to result from the adoption of QC systems and programs. During the months this program has been developing, inspectors have been informed of the goals and objectives of the Department's effort, the reasons for it, and the benefits to individual employees and the inspection cadre as a whole which should result from QC. The Department's inspection force is now demonstrating considerable interest in QC. In the past, inspectors have shown their integrity by supporting and administering new initiatives and the Secretary has confidence that will occur with QC.

25. More industry freedom. There was a suggestion in one comment that plants could develop their own QC systems as desired and if successful, would eliminate the need for review and monitoring by the Department.

This suggestion contemplated that the Department should establish a policy to allow plants to develop and implement quality control systems without prior approval and that the Department could institute a method for spot-checking the plants to determine whether or not the quality control system is adequate and effective. The suggestion implies that the plants could and would develop and implement QC systems that adequately satisfy regulatory requirements.

The Department's experience with partial QC programs has not shown the feasibility of such an approach, even if there were no other constraints. In many cases the submitters are convinced that their QC programs are more than adequate. Upon further review by the Department, some QC programs are found to be inadequate. Moreover, total plant QC would be a new experience. In order for the Department to assure adequate consumer protection, it is essential that the Administrator evaluate the total plant QC system or partial QC program prior to approval and implementation.

26. Use of AQL's. One comment indicated the Agency should develop Accepted Quality Level (AQL) programs for food inspectors to use for various products instead of the total plant quality control system proposed.

This comment suggests that sampling and examination (or analysis) of a finished product is preferable—and in some way assures good manufacturing practices—to "process control" backed up by occasional finished production examination and analysis. The Department has extensive experience with AQL programs which have in fact been very useful and beneficial. However, the Department has found that controlling a production process at key control points, thereby "preventing" problems (as a QC system can), can be far more effective and efficient than AQL programs.

The Final Rule

After reviewing the comments received, the Department has determined that the provisions of the proposal should be adopted for the (1) application for total plant and partial plant quality control, (2) evaluation and approval of total plant and partial plant quality control, (3) termination of total plant and partial plant quality control, and (4) use of a uniform QC logo or symbol on products produced in a plant

with an approved QC system. In addition, a new provision is included in the final rule so that a plant with an approved total QC system can produce a new product for test-marketing for up to 6 months without prior submission of a quality control procedure for that product. Under this special procedure, the plant will submit adequate data to the inspector-in-charge so that he can determine that the label has been approved for the new product and that the processor's method for controlling the process and product will assure that all Federal requirements are met.

Editorial changes have been made in the final rule to coincide with the stated conventional terminology, and eliminate the abbreviations of quality control. The term "poultry food product" as used in the proposal has been modified to "poultry product" so that the regulations would apply to this larger class of product. This was the Department's original intent.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS: REINSPECTION AND PREPARATION OF PRODUCTS

Therefore, § 318.4 of the Federal meat inspection regulations (9 CFR 318.4) is amended by changing the section heading and the Table of Contents, by rewording the second and third sentences of paragraph (b), and by adding new paragraphs (c), (d), (e), (f), and (g) to read as follows:

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

(b) * * * In order to carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to assure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter. The effectiveness of such measures will be subject to review by the Department.

(c) *Applying for Total Plant Quality Control.* Any owner or operator of an official establishment preparing meat food product who has a total plant quality control system or plan for controlling such product, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total

Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control system requires it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system; an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent of or not predominantly production responsibilities. In the case of an establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will be responsible for the quality control system.

(3) A list identifying those Parts and sections of the Federal meat inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the quality control system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters or limits which will be used, and the points at which corrective action will occur and the nature of such corrective action—ranging from least to most severe: *Provided*, That, subsequent to approval of the total plant quality

control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d) *Applying for Partial Quality Control.* Any owner or operator of an official establishment preparing meat food products who has a quality control program for a product, operation, or a part of an operation, may submit it to the Administrator and request a determination as to whether or not that program is adequate to result in product being in compliance with the requirements of the Act. Such a request shall, as a minimum, include:

(1) A letter from the establishment official responsible for quality control stating the objective of the program, and that all data and information generated by the program will be maintained to enable the Department to monitor compliance and available to Department personnel.

(2) Detailed information concerning raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will occur, and the nature of the corrective action—ranging from the least to the most severe.

(e) *Evaluation and Approval of Total Plant Quality Control or Partial Quality Control.* (1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) or (d) of this section. If it is determined by the Administrator on the basis of the evaluation, that the total quality control system or partial quality control program will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulations thereunder, the total quality control system or partial quality control program will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system or program is found by the Administrator to be unacceptable, formal notification shall be given to the

applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system or program in accordance with the notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system or partial quality control program to assure compliance with the requirements of the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out his responsibilities under the Act.

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by Parts 316 and 317 of this subchapter.



(g) *Termination of Total Plant Quality Control or Partial Quality Control.*

(1) The approval of a total plant

quality control system or a partial quality control program may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system or partial quality control program may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded meat food product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating the approval. In those instances where there is conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system or program to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be provided to the establishment owner or operator to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total plant quality control system or partial quality control program has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total plant quality control system will not be evaluated by the Administrator for at least 6 months from the termination date, or for at least 2 months from the termination date in the case of a partial quality control program.

(Secs. 5, 8, 21, 202, and 407 34 Stat. 1260, as amended, 21 U.S.C. 605, 608, 621, 642, and 677; 42 FR 35625, 35626, 35631)

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

Further, § 381.145 of the poultry products inspection regulations (9 CFR 381.145) is amended as follows:

1. The paragraph designation "(c)" would be deleted and the present text of that paragraph (c) would be added to the end of paragraph (b) of that section.

2. New paragraphs (c), (d), (e), (f), and (g) would be added to read as follows:

§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

(c) *Applying for Total Plant Quality Control.* Any owner or operator of an official establishment preparing poultry product who has a total plant quality control system or plan for controlling such products, after ante-mortem and post-mortem inspection, through all stages of preparation, may request the Administrator to evaluate it to determine whether or not that system is adequate to result in product being in compliance with the requirements of the Act and therefore qualify as a U.S. Department of Agriculture (USDA) Total Plant Quality Control Establishment. Such a request shall, as a minimum, include:

(1) A letter to the Administrator from the establishment owner or operator stating the company's basis and purpose for seeking an approved quality control system and willingness to adhere to the requirements of the system as approved by the Department; that all the establishment's data, analyses, and information generated by its quality control system will be maintained to enable the Department to monitor compliance and available to Department personnel; that plant quality control personnel will have authority to halt production or shipping of product in cases where the submitted quality control systems require it; and that the owner or operator (or his/her designee) will be available for consultation at any time Department personnel consider it necessary.

(2) In the case of an establishment having one or more full-time persons whose primary duties are related to the quality control system, an organizational chart showing that such people ultimately report to an establishment official whose quality control responsibilities are independent

of or not predominantly production responsibilities. In the case of a small establishment which does not have full-time quality control personnel, information indicating the nature of the duties and responsibilities of the person who will also be responsible for the quality control system.

(3) A list identifying those Subparts and sections of the poultry products inspection regulations which are applicable to the operations of the establishment applying for approval of a quality control system. This list shall also identify which part of the system will serve to maintain compliance with the applicable regulations.

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters of limits which will be used and the points at which corrective action will occur, and the nature of such corrective action—ranging from the least to most severe. *Provided*, That subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d) *Applying for Partial Quality Control.* Any owner or operator of an official establishment preparing poultry products who has a quality control program for a product, operation, or a part of an operation, may submit it to the Administrator and request a determination as to whether or not that program is adequate to result in product being in compliance with the requirements of the Act. Such a request shall, as a minimum, include:

(1) A letter from the establishment official responsible for quality control stating the objective of the program, and that all data and information generated by the program will be maintained to enable the Department to monitor compliance and available to Department personnel.

(2) Detailed information concerning raw material control, the critical check or control points, the nature and frequency of tests to be made, the charts and records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the limits which will be used and the points at which corrective action will occur; and the nature of the corrective action—ranging from the least to the most severe.

(e) *Evaluation and Approval of Total Plant Quality Control or Partial Quality Control.* (1) The Administrator shall evaluate the material presented in accordance with the provisions of paragraph (c) or (d) of this section. If it is determined by the Administrator, on the basis of the evaluation, that the total quality control system or partial quality control program will result in finished products controlled in this manner being in full compliance with the requirements of the Act and regulation thereunder, the total quality control system or partial quality control program will be approved and plans will be made for implementation under departmental supervision.

(2) In any situation where the system or program is found by the Administrator to be unacceptable, formal notification shall be given to the applicant of the basis for the denial. The applicant will be afforded an opportunity to modify the system or program in accordance with this notification. The applicant shall also be afforded an opportunity to submit a written statement in response to this notification of denial and a right to request a hearing with respect to the merits or validity of the denial. If the applicant requests a hearing and the Administrator, after review of the answer, determines the initial determination to be correct, he shall file with the Hearing Clerk of the Department the notification, answer and the request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with Rules of Practice which shall be adopted for this proceeding.

(3) The establishment owner or operator shall be responsible for the effective operation of the approved total plant quality control system or partial quality control program to assure compliance with the requirements of the Act and regulations thereunder. The Secretary shall continue to provide the Federal inspection necessary to carry out the responsibilities of the Act.

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any labeling, the following logo. Any labeling bearing the logo and any wording of explanation with respect to this logo shall be approved as required by Subparts M and N of this Part.



(g) *Termination of Total Plant Quality Control or Partial Quality Control.* (1) The approval of a total plant quality control system or a partial quality control program may be terminated at any time by the owner or operator of the official establishment upon written notice to the Administrator.

(2) The approval of a total plant quality control system or partial quality control program may be terminated upon the establishment's receipt of a written notice from the Administrator under the following conditions:

(i) If adulterated or misbranded poultry product is found by the Administrator to have been prepared for or distributed in commerce by the subject establishment. In such case, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of terminating

the approval. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of approval shall remain in effect pending the final determination of the proceeding.

(ii) If the establishment fails to comply with the quality control system or program to which it has agreed after being notified by letter from the Administrator or his designee. Prior to such termination, opportunity will be provided to the establishment owner or operator to present views to the Administrator within 30 days of the date of the letter. In those instances where there is a conflict of facts, a hearing, under applicable Rules of Practice, will be afforded to the establishment owner or operator, if requested, to resolve the conflict. The Administrator's termination of quality control approval shall remain in effect pending the final determination of the proceeding.

(3) If approval of the total plant quality control system or partial quality control program has been terminated in accordance with the provisions of this section, an application and request for approval of the same or a modified total plant quality control system will not be evaluated by the Administrator for at least 6 months from the termination date, or for at least 2 months from the termination date in the case of a partial quality control program.

(Secs. 7, 11(b), 14, 16 and 22, 71 Stat. 441, as amended, 21 U.S.C. 456, 460(b), 463, 465, and 467d; 42 FR 35625, 35626, and 35631)

Done at Washington, D.C., on: August 12, 1980.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

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